Minutes of the March 13, 2014, meeting of the

South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, March 13, 2014, at 10:00 a.m. in the Board Room at the South Carolina Department of Health and Environmental Control building, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Chairman
Member-At-Large

Mark Lutz, Vice-Chairman
1st District

Ann B. Kirol, DDS, Secretary
5th District

R. Kenyon Wells
2nd District

Charles M. Joye, II, P.E.
3rd District

L. Clarence Batts
4th District

John O. Hutto, Sr., MD
6th District

Also in attendance were Catherine B. Templeton, Director; W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and members of the public. (Attachment 0-2)

Chairman Amsler called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item1: Recognition of JP Strom Award recipient

Ms. Regina Erving, Director, Bureau of Drug Control, introduced Michael Ritchie who joined DHEC Drug Control in June 2013 and began his training as a drug inspector with the Bureau. He completed his law enforcement mandatory training at the SC Criminal Justice Academy on January 24, 2014, and was awarded the highest recognition offered by the Academy. The J. P. Strom Award is presented to the member of the graduating class who has achieved the highest grade point average during the twelve-week basic training program for SC Class I law enforcement officers.

Item 2: Agency Affairs

Director Templeton briefed the Board on the Budget request, SUPERB Fund payment adjustments, Blue Ribbon Committee recommendations status in the General Assembly, and Department work on Regulation Review Committee recommendations.

The Board accepted this as information.

Item 3: Board Minutes of the January 9, 2014 meeting (Attachment 3-1)

Mr. Batts moved, seconded by Mr. Joye, to approve the minutes as submitted for the January 9, 2014, meeting. The Board voted and Motion carried.

Item 4: Administrative and Consent Orders issued by Environmental Affairs (Attachment 4-1)

Ms. Robin Stephens, Assistant to the Deputy Director, EQC, stated six (6) Administrative Orders and fifty (50) Consent Orders had been issued with total penalties of $137,499.

After discussion, ***the Board accepted this item as information.***

Item 5: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 5-1)

Ms. Melinda Bradshaw, Health Regulation Liaison, stated one (1) Consent Order had been issued with a penalty of $5,000.

The Board accepted this item as information.

Item 6: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-9, Water Pollution Control Permits, State Register Document No. 4444, Legislative Review is required (Attachment 6-1)

Mr. David Wilson, Director, Bureau of Water, presented this item to the Board.

Regulation 61-9 establishes wastewater and sludge permitting requirements for discharges to the land and surface waters of the state. Related to this agenda item, sections 503 and 504 address land application of sludge, which is a by-product of wastewater treatment systems. Sludge, also known as biosolids, is recycled nationally by farmers because of the nutrient value typically in sludge and because sludge has soil conditioning value. In regulation of this material for beneficial use (recycling), care must be given to pollutants that could impact public health and the environment.

The Department was notified in July 2013 of polychlorinated biphenyls (PCB) contaminated material in three publicly owned treatment works (POTWs) located in upstate South Carolina. Because PCBs were banned in the United States over thirty years ago, they are not expected to be found in wastewater systems. The Department's investigation indicated the materials found in the POTWs were illicitly discharged into the systems and originated from unknown sources. It was believed these illicit discharges were limited to upstate POTWs until September 2013 when PCB contaminated material was detected in a restaurant grease trap in Richland County. Therefore, the Department found there was a significant risk that illicit discharges of PCBs may be occurring statewide, and it was appropriate to take immediate action to prohibit land application of PCB contaminated material via an emergency regulation (September 25, 2013).

PCBs are chemicals that were used as coolants and lubricants in transformers, capacitors, and other electrical equipment before being significantly restricted by Congress in 1979 because of evidence that they build up in the environment and can cause adverse health effects. Once in the environment, PCBs do not readily break down and therefore remain in the environment for long periods of time cycling through the air, water, and soil. PCBs are taken up in small organisms and fish. PCBs can accumulate in leaves and the above-ground parts of plants and food crops.

The Department proposed that the amendments to R.61-9 would strengthen and improve the existing regulation and make appropriate revisions to the portions related to land application of sludge by establishing restrictions on land application of sludge with PCBs.

A public hearing was conducted with several persons in attendance who spoke on this regulation amendment. (Attachment 6-2) The written comments that were provided to the Clerk by the speakers at the public hearing are included in the permanent record. (Attachment 6-3)

After discussion, ***Mr. Batts moved, seconded by Dr. Kirol, to go into Executive Session for the purpose of obtaining legal advice pertaining to the matter being discussed. The Board voted and Motion carried.***

Chairman Amsler announced the Board was back in public session and while in Executive Session, no actions were taken.

After further discussion, ***Mr. Batts moved, seconded by Mr. Lutz, to find for the need and reasonableness of Proposed Regulation 61-9, Water Pollution Control Permits, and approve them for submission to the Legislature for review with the following revisions that were raised, considered, or discussed by public comment:***

a. ***Add "as soon as practical" to paragraph 2 and 3 of Section 503 and Section 504;***
b. ***Add "consistent with applicable laws" to paragraph 4 of Section 503 and Section 504;***
c. ***Use a land measurement PCB level to initiate further action beyond monitoring and reporting to DHEC;***
d. ***Add Sunset Provision at end of five (5) years.***

Mr. Joye moved, seconded by Mr. Batts, to amend the initial Motion as follows:

a. ***Move paragraph 4 into paragraph 3 of Section 503 and Section 504;***
b. ***Delete the land application standard.***

The Board voted and the Motion to amend carried.

The Board voted and Initial Motion as amended carried.

A verbatim transcript of this proceeding is included as part of the permanent record. (Attachment 6-4)

Item 7: Proposed Amendments to Regulation 61-30, Environmental Protection Fees (Attachment 7-1)

Mr. Robbie Brown, Director, Division of Air Assessment and Regulation, presented this item to the Board.

The South Carolina Department of Health and Environmental Control (Department) proposes to amend Regulation 61-30.G(3), Schedule of Air Quality Fees, to increase fees in order to cover the cost of its Title V permit program. The Clean Air Act requires that states establish fees to administer the Title V permit program that are sufficient to cover all reasonable (direct and indirect) costs. These fees should cover the costs of administering the program and include those activities listed in Section 502(b)(3)(a) of Title V of the 1990 amendments to the Federal Clean Air Act.

The Clean Air Act, 42 U.S.C. 7401, *et seq.*, sets forth the minimum requirements for air quality in the United States and requires states to develop and maintain a Title V permit program. 40 C.F.R. Section 70.9(b)(1) provides "...[t]he State program shall establish a fee schedule that results in the collection and retention of revenues sufficient to cover the permit program costs."

S.C. Code Ann. Section 1-23-120(H), provides that amendments made to comply with federal law do not require legislative review. Therefore, this amendment, because it is being promulgated to comply with federal law, does not require legislative review.

After discussion, ***Mr. Lutz moved, seconded by Dr. Kirol, to grant approval to publish a Notice of Proposed Regulation in the*** **State Register,** ***to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.***

Item 8: Approval of proposed addition to the state pre-hospital Emergency Medical Services (EMS) drug formulary (Attachment 8-1)

Ms. Melinda Bradshaw, Health Regulation Liaison, presented this item to the Board.

The EMS Act (Code 44-61-130) states "Emergency medical technicians, trained to provide advanced life support and possessing current Department of Health and Environmental Control certification while on duty with a licensed service, are authorized to possess limited quantities of drugs, including controlled substances, as may be approved by the Department of Health and Environmental Control for administration to patients during the regular course of duties of emergency medical technicians, pursuant to the written or verbal order of a physician possessing a valid license to practice medicine in this State; however, the physician must be registered pursuant to state and federal laws pertaining to controlled substances."

EMS Agencies are unable to purchase any of the medications currently listed in the state pre-hospital Emergency Medical Services (EMS) drug formulary used for rapid sequence intubation (RSI) due to multiple pharmaceutical manufacturing backorders. It is anticipated that EMS agencies will be without access to these medications for at least another 30 days or more. There is not a substitute procedure for RSI when it is indicated and failure to use RSI on a needing RSI could result in worsening hypoxia form poor airway control and led to an increase in patient morbidity and mortality.

The EMS Medical Control Committee, while addressing periodic pharmaceutical backorder of medications currently used in the state pre-hospital protocols for RSI, has recommended the addition of Ketamine to the EMS drug formulary for use in RSI, extreme pain management, conscious sedations and excited delirium. Ketamine was approved for submission to the Board by the Medical Control Physicians' Committee and the EMS Advisory Council of the Division of EMS and Trauma.

After discussion, ***Mr. Batts moved, seconded by Dr. Kirol, to approve the addition of Ketamine to the state approved pre-hospital drug formulary and direct staff to develop administrative and training guidance to fully implement this drug into the paramedic training curriculum. The Board voted and Motion carried.***

Item 9: Hospital Infection Disclosure Act (HIDA) Advisory Committee Membership Nomination (Attachment 9-1)

Ms. Katherine Habicht, Division of Acute Epidemiology, presented this item to the Board.

S.C. Code Section 44-7-2430 (C)(1) states: The Board of Health and Environmental Control shall appoint an advisory committee that must have an equal number of members representing all involved parties. The Board shall seek recommendations for appointments to the advisory committee from organizations that represent the interests of hospitals, consumers, businesses, purchasers of health care services, physicians, and other professionals involved in the research and control of infections.

The Board of the Palmetto Chapter of the Association for Professionals in Infection Control (APIC Palmetto) has nominated Ms. Virginia Herring to replace Ms. Cindy Buddlemann as a HIDA member representing the APIC Palmetto.

Ms. Herring holds a Bachelor of Arts in Psychology from Columbia College in Columbia, SC and a Bachelor of Science in Nursing from the University of South Carolina in Columbia, SC. Ms. Herring has a strong nursing background with experiences in surgical nursing, quality improvement and infection prevention. She been employed by Palmetto Richland since 2005 as an Infection Preventionist and is currently responsible for whole house surveillance of Central Line Associated Bloodstream Infections (CLABSI) and Ventilator Associated Pneumonia (VAP). She obtained her Certification in Infection Control in 2005 and was re-certified in 2010.

After discussion, ***Mr. Wells moved, seconded by Mr. Lutz, to appoint Virginia Herring as a member of the Hospital Infection Disclosure Act (HIDA) Advisory Committee, based on the recommendation of APIC Palmetto, an organization of professionals involved in the control of infections. The Board voted and Motion carried.***

Item 10: Placement of Alfaxalone into Schedule IV for Controlled Substances (Attachment 10-1)

Ms. Regina Irving, Director, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule IV substances are listed in § 44-53-250. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

§ 44-53-160(C) states: "If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change."

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on February 27, 2014, a final order to schedule alfaxalone, including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA), effective on March 31, 2014. F.R. Volume 79, Number 39, pp. 10985-10989.

The Assistant Secretary of the Department of Health and Human Services and the Administrator of the DEA found alfaxalone meets the necessary findings on the potential for abuse, currently accepted medical use, and physical or psychological dependence for placement in schedule IV.

Alfaxalone is a neurosteroid derivative of 11-alpha-hydroxy-progesterone and has central nervous system (CNS) depressant properties. On October 23, 2012, the Food and Drug Administration (FDA) published a final rule to approve alfaxalone (Alfaxan®) for marketing as an intravenous injectable anesthetic for the induction and maintenance of anesthesia in cats and dogs. Federal law currently restricts alfaxalone to use by, or on the order of, a veterinarian such that it may only be administered. Alfaxalone may not be prescribed by a veterinarian, nor dispensed by a pharmacist pursuant to a prescription.

Alfaxalone is similar to the actions of barbiturates like phenobarbital (schedule IV) and methohexital (schedule IV), benzodiazepines such as diazepam (schedule IV) and midazolam (schedule IV), as well as the anesthetic agents propofol (proposed to be controlled as a schedule IV substance) and fospropofol (schedule IV).

As a result of the DEA order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, and engage in research, conduct instructional activities, and possess), or propose to handle alfaxalone and substances containing alfaxalone.

After discussion, ***Mr. Lutz moved, seconded by Mr. Batts, adopt the final scheduling of the Alfaxalone as defined in the Board package and Federal Register Volume 79, Number 39, pp. 10985-10989 and amend Section 44-53-250 by adding and designating the same substances into Schedule IV of the South Carolina Controlled Substances Act. The Board voted and Motion carried.*** (Board Designation Attachment 10-2)

Item 11: Legal Report

None.

Item 12: Final Review Conference – Docket No. 14-RFR-2, denial of Trident Medical Center's request for the establishment and licensure of a new Level III subspecialty perinatal unit with four NICU bassinets to be located in a renovated portion of the second floor of Trident Medical Center (Attachment 12-1)

Mr. Taylor introduced the matter to the Board. Ms. Ashley C. Biggers represented the Department. Mr. William Thomas represented Trident Medical Center. Mr. Stuart Andrews represented Medical University of South Carolina which was permitted to provide information supporting the staff decision. Trident Medical Center presentation to Board and additional

information to be added to the administrative record in the matter is included as part of the record. (Attachment 12-2)

After presentations and discussion, ***Mr. Batts moved, seconded by Dr. Kirol, to go into Executive Session for the purpose of deliberating and obtaining legal advice pertaining to the matter being discussed. The Board voted and Motion carried.***

Chairman Amsler announced the Board is back in public session. While in Executive Session, no actions were taken.

After further discussion, ***Mr. Batts moved, seconded by Mr. Lutz, to uphold the staff decision to deny Trident Medical Center's request for the establishment and licensure of a new Level III subspecialty perinatal unit with four NICU bassinets to be located in a renovated portion of the second floor of Trident Medical Center. The Board voted and Motion carried by a vote of 5-1 with Mr. Wells being the opposing vote.***

Chairman Amsler adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,

Ann B. Kirol, DDS, Secretary

Minutes approved this 8th day of May 2014.

ATTEST:

Allen Amsler, Chairman

Attachments

0-1 Agenda
0-2 Attendance Roster
3-1 Minutes of January 9 meeting
4-1 Administrative Orders, Consent Orders issued by Environmental Affairs
5-1 Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation
6-1 Proposed Amendment of R.61-9, Water Pollution Control Permits, State Register Document No. 4444
6-2 Public hearing sign-in sheet
6-3 Comments submitted by speakers at public hearing
6-4 Verbatim Transcript
7-1 Proposed Amendment of R.61-30, Environmental Protection Fees
8-1 Approval of proposed addition to the state pre-hospital Emergency Medical Services (EMS) drug formulary
9-1 Hospital Infection Disclosure Act (HIDA) Advisory Committee Membership Nomination
10-1 Placement of Alfaxalone into Schedule IV for Controlled Substances
12-1 Final Review Conference – Docket No. 14-RFR-2, Trident Medical Center
12-2 Trident Medical Center presentation to Board and additional information to be added to record